I have by certify that this correspondence is being deposited with the United States Postal Service as First Class Mail and envelope addressed to Assistant Commissioner for Patents, Washington, D.C., 20231, on the date indicated

BY: Tourantrain

DATE: December 9 200

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:

Patent Application of

: Attention:

Reiner Class et al.

: OIPE

Conf. No.:

7581

: International Appln. No.

PCT/US00/21747

Appln. No.:

10/049,753

Group Art Unit:

Filed:

9 August 2000

Not Yet Assigned

For:

Antimicrobial Histone H1 Compositions,

: Attorney Docket

Kits, and Methods of Use Thereof

No. 10573-1U1

# PETITION TO WITHDRAW HOLDING OF ABANDONMENT PURSUANT TO 37 C.F.R. §1.8(b)

The Applicants respectfully petition the Commissioner to withdraw the holding of abandonment of the above-referenced application. The enclosed "Notice of Abandonment Under 37 CFR 1.53 (f) or (g)" dated November 27, 2002 for failure to respond to the "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States

Designated/Elected Office (DO/EO/US)" dated April 5, 2002 was received by the Applicants' representative on December 4, 2002. The Applicants respectfully submit that a response to the Notification was filed by the Applicants' representative on October 7, 2002 (with a petition for a four-month extension of time, October 5 and 6, 2002 being Saturday and Sunday).

The Applicants hereby state that:

- On April 16, 2002, the Applicants' representative received a "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" mailed by the Office on April 5, 2002).
- 2. On October 7, 2002, the Applicants' representative mailed a "Transmittal of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" to the Office, using the certificate of mailing procedure of 37 C.F.R. §

1.8(a), in an enveloped addressed to "Assistant Commissioner for Patents, Washington DC, 20231" and accompanied by a "Petition for Extension of Time Under 37 C.F.R. §1.136(a)." The Petition extended the period for responding to the Notice through October 7, 2002 (October 5 and 6, 2002 being Saturday and Sunday). True copies of these documents, their enclosures, and a post card which accompanied the documents accompany this Petition.

3. Also accompanying this Petition is a "Statement of Helene Gabel." In the Statement, Ms. Gabel avers that she signed the Certificate of Mailing that appears atop the "Notification" of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)," and that she deposited the document with the United States Postal Service on the date indicated, namely October 7, 2002.

Accordingly, it is respectfully requested that the holding of abandonment of this application be withdrawn and that the referenced application be reinstated.

The Applicants believe that there is no fee required with respect to this Petition. However, in the event any fee is necessary, please charge such fee to Deposit Account No. 50-1017 (Billing No. 210147.0002).

A favorable first Office Action on the merits is respectfully requested at the earliest possible time.

Respectfully submitted,

Reiner Class, et al.

CLEMBO, 200 By: 2 Gary D. Colby, Ph.D., J.D.

Registration No. 40,961

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.

One Commerce Square

2005 Market Street - Suite 2200

Philadelphia, PA 19103-7086

Telephone:

215-965-1200

Direct Dial:

215-965-1285

Facsimile:

215-965-1210

E-Mail:

gcolby@akingump.com





#### DUCUMENT HAS A COLORED BACKGROUND. SECURITY FEATURES LISTED ON BACK

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
DISBURSEMENT ACCOUNT
A REGISTERED LIMITED LIABILITY PARTNERSHIP
INCLUDING PROFESSIONAL CORPORATIONS
1333 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC. 20036
(202) 887-4000

EIGHT HUNDRED ONE AND 00/100 DOLLARS

Citibank. Delaware One Penns Way New Castle DE 19720

Check No.

38146

62-20/311

DATE 10/07/2002

AMOUNT OF CHECK

\$ \*\*\*\*\*\*\*801.00

**VOID AFTER 6 MONTHS** 

TO THE ORDER OF DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

AUTHORIZED SIGNATURE

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AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P. DISBURSEMENT ACCOUNT

A REGISTERED LIMITED LIABILITY PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS 1333 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20036 (202) 887-4000

Citibank, Dolaware One Penns Way New Castle DE 19720

Check No.

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\_\_DATE\_\_10/07/2002

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EIGHT HUNDRED ONE AND 00/100 DOLLARS

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**VOID AFTER 6 MONTHS** 

TO THE ORDER OF

**DIRECTOR OF THE UNITED STATES PATENT AND** 

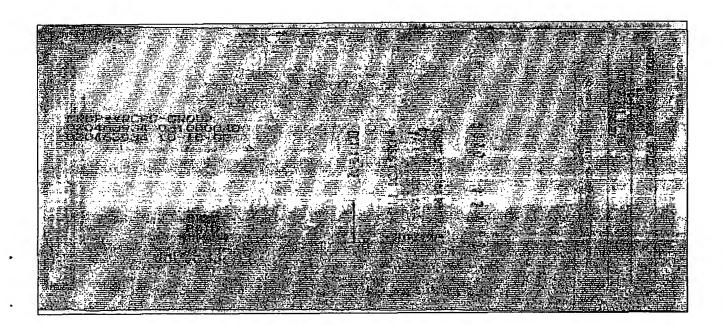
TRADEMARK OFFICE

**AUTHORIZED SIGNATURE** 

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Account 38641612 Serial Number Amount 38146

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Bank ID 3110020

Sequence 600633209 Location

Paid Date 10/16/2002

Customer Data 000000





APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY. DOCKET NO./TITLE

10/049,753

Reiner Class

10573-1U1

Gary D Colby Akin Gump Strauss Hauer & Feld One Commerce Square 2005 Market Street, Suite 2200 Philadelphia, PA 19103

CONFIRMATION NO. 7581 ABANDONMENT/TERMINATION **LETTER** \*OC000000009164848\*

Date Mailed: 11/27/2002

# NOTICE OF ABANDONMENT UNDER 37 CFR 1.53 (f) OR (g)

The above-identified application is abandoned for failure to timely or properly reply to the Notice to File Missing Parts (Notice) mailed on 04/05/2002.

No reply was received.

A petition to the Commissioner under 37 CFR 1.137 may be filed requesting that the application be revived.

Under 37 CFR 1.137(a), a petition requesting the application be revived on the grounds of UNAVOIDABLE DELAY must be filed promptly after the applicant becomes aware of the abandonment and such petition must be accompanied by: (1) an adequate showing of the cause of unavoidable delay; (2) the required reply to the aboveidentified Notice; (3) the petition fee set forth in 37 CFR 1.17(I); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Under 37 CFR 1.137(b), a petition requesting the application be revived on the grounds of UNINTENTIONAL DELAY must be filed promptly after applicant becomes aware of the abandonment and such petition must be accompanied by: (1) a statement that the entire delay was unintentional; (2) the required reply to the aboveidentified Notice; (3) the petition fee set forth in 37 CFR 1.17(m); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Any questions concerning petitions to revive should be directed to "Office of Petitions" at (703) 305-9282.

A'copy of this notice MUST be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C., 20231, on the date indicated below 1.1

below. Helens Sahe

DATE: Oche

1,200>

**PATENT** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:

Patent Application of

: Attention:

Reiner Class et al.

: Box PCT

Conf. No.:

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Appln. No.:

10/049,753

Group Art Unit:

Filed:

9 August 2000

Not Yet Assigned

For:

Antimicrobial Histone H1 Compositions,

: Attorney Docket

Kits, and Methods of Use Thereof

No. 10573-1U1

# TRANSMITTAL OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated 5 April 2002, we submit herewith the following:

- [X] Copy of the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US), mailed 5 April 2002.
- [X] Executed Declaration and Power of Attorney.
- [X] Information Disclosure Statement, PTO/SB/08A and/or PTO/SB/08B, and cited references.
- [X] Preliminary Amendment.
- [X] Statement Regarding Nucleotide and/or Amino Acid Sequence Submission Requirement
- [X] Petition for Extension of Time along with requisite fee.
- [ ] Request for Refund.
- [ ] Request for Corrected Filing Receipt. Attached is a marked-up copy of the Filing Receipt showing corrections.
- [X] Applicant(s), by its/their undersigned attorney, claim(s) Small Entity Status under 37 C.F.R. §1.27 as [] an Independent Inventor, or [X] a Small Business Concern, or [] a Non-Profit Organization.



## Additional claim fees are calculated as follows:

|            |   |      |                                       | SMALL            | ENTITY | LARGI      | ENTITY |               |
|------------|---|------|---------------------------------------|------------------|--------|------------|--------|---------------|
|            | CLAIMS<br>REMAINING<br>AFTER<br>AMENDMENT |      | HIGHEST NO.<br>PREVIOUSLY<br>PAID FOR | PRESENT<br>EXTRA | RATE   | ADDIT. FEE | RATE   | ADDIT.<br>FEE |
| TOTAL      | 46  | (-)  | 37                                    | 9                | x\$9   | 81         | x\$18  |               |
| INDEP.     | 3   | (-)  | 3                                     | 0                | x\$42  | 1          | x\$84  |               |
| I I 1st PR | ESENTATION OF                             | MULT | PLE DEPENDENT                         | CLAIMS           | +\$140 |            | +\$280 |               |
|            |   |      |                                       |                  | TOTAL  | 81.00      | TOTAL  |               |

- [X] The following fees noted below are being paid.
  - Surcharge of \$130 for late filing of English translation.
  - [X]Extension of Time fee in the amount of \$720.00 (Petition for Extension of Time is attached).
  - XAdditional Claim Fee in the amount of \$81.00 calculated above.
- [X] Enclosed is our firm's check in the amount of \$801.00 for the above fee(s).
- The Commissioner is hereby authorized to charge and/or credit Deposit Account No. 50-1017 (Billing No. 210573.0002) as noted below. A duplicate copy of this sheet is enclosed.
  - The above-calculated fee(s) calculated totaling \$ .00.
  - Any overpayments or deficiencies in the above-calculated fee(s). **[X]**
  - [X]Any additional fees required under 37 C.F.R. § 1.16 or § 1.17.
  - [X]In the event that a Petition for Extension of Time is required during the prosecution of this application, but not submitted, please charge any extension fee under 37 C.F.R. § 1.136(a) to our Deposit Account noted above.

CORRESPONDENCE ADDRESS

7 October 200c By:

Jary D. Colby, Ph.D., J.D.

Registration No. 40,961

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.

One Commerce Square

2005 Market Street - Suite 2200

Philadelphia, PA 19103-7086

Telephone:

215-965-1200

Direct Dial: 215-965-1285

Facsimile:

215-965-1210

E-Mail:

gcolby@akingump.com

GDC:hxg **Enclosures** 





U.S APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/049.753

Reiner Class

10573-1U1

PCT/US00/21747

I.A. FILING DATE

PRIORITY DATE

08/09/2000

CONFIDM

CONFIRMATION NO. 7581
371 FORMALITIES LETTER

OC000000007787527°

Gary D Colby Akin Gump Strauss Hauer & Feld One Commerce Square 2005 Market Street, Suite 2200 Philadelphia, PA 19103

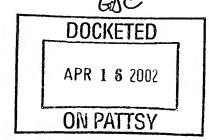


Date Mailed: 04/05/2002

# NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report



The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

 Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

The following items MUST be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):
  - This application does not contain a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).

DEADLINE: 6/5/02



- A copy of the "Sequence Log" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
  - APPLICANT MUST PROVIDE:
    - an initial or substitute computer readable form (CRF) of the "Sequence Listing."
    - An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
  - For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
    - For Rules Interpretation, call (703) 308-4216
    - To Purchase Patentin Software, call (703) 306-2600
    - □ For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov
    - This application does not contain a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).
    - A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

#### KAREN M WILLIAMS

Telephone: (703) 305-3688

#### PART 1 - ATTORNEY/APPLICANT COPY

|                             | A Company of the Comp |                  |
|-----------------------------|--|------------------|
| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO.  | ATTY, DOCKET NO. |
| 10/049,753                  | PCT/US00/21747   | 10573-1U1        |

FORM PCT/DO/EO/905 (371 Formalities Notice)





# DECLARATION AND POWER OF ATTORNEY (Related Application)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Antimicrobial Histone H1 Compositions, Kits, and Methods of Use Thereof the specification of which is attached hereto and/or was filed on February 11, 2002 as Application No. 10/049, 753

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:



# FOREIGN PRIORITY APPLICATION(S)

|          |           |                        | Priority Claimed  [] Yes [] No |
|----------|-----------|------------------------|--------------------------------|
| (Number) | (Country) | (Day/month/year filed) |                                |
|          |           |                        | Priority Claimed               |
|          |           |                        | _ [] Yes [] No                 |
| (Number) | (Country) | (Day/month/year field) |                                |

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional patent application(s) listed below and have also identified below any United States provisional patent application(s) having a filing date before that of the application on which priority is claimed.

#### PROVISIONAL PRIORITY PATENT APPLICATION

|                   |               | Priority Claimed |
|-------------------|---------------|------------------|
| <br>              |               | [] Yes [] No     |
| (Application No.) | (Filing Date) |                  |
|                   |               | [] Yes [] No     |
| (Application No.) | (Filing Date) |                  |

I hereby claim the benefit under Title 35, United States Code, Section 120, of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or in the prior U.S. provisional application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose information material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56, which occurred between the filing date of the prior application and the national or PCT international filing date of this application:



| PCT/US00/21747           | August 9, 2000  | Pending                                |
|--------------------------|-----------------|--|
| (Application Serial No.) | (Filing Date)   | (Status)(patented, pending, abandoned) |
| 09/372,500               | August 11, 1999 | Pending                                |
| (Application Serial No.) | (Filing Date)   | (Status)(patented, pending, abandoned) |

And I hereby appoint the registered attorneys and agents associated with AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P., Customer No. 000570, as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence to Customer No. 000570, namely, AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P., One Commerce Square, 2005 Market Street, Suite 2200, Philadelphia, Pennsylvania 19103. Please direct all communications and telephone calls to Gary D. Colby at (215) 965-1285.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| Full name of first        |                    |                              |
|---------------------------|--------------------|------------------------------|
| joint inventor            | Reiner Class       |                              |
| Inventor's Signature      | arios              | A                            |
| Date05-0                  | <u>1-02</u>        |                              |
| Residence <u>Drexel I</u> | Hill, Pennsylvania |                              |
| Citizenship <u>German</u> | у                  |                              |
| Post Office Address       | 53-7 Revere        | e Road; Drexel Hill PA 19026 |





Full name of second joint inventor Michael Zeppezauer

Inventor's Signature Mnhael Gyperaum

Date 2nd APR/L 200 2

Residence Scheidt, Saarbruken, Germany

Citizenship Germany

Post Office Address Auf den Hutten 32; Sheidt/Saarburken; Germany



Thereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C., 20231, on the date indicated below.

BY: Velene Hale

DATE: October

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:

Patent Application of

: Attention:

Reiner Class et al.

: Box PCT

Conf. No.:

7581

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Appln. No.:

10/049,753

: Group Art Unit:

Filed:

9 August 2000

: Not Yet Assigned

For:

Antimicrobial Histone H1 Compositions,

: Attorney Docket

Kits, and Methods of Use Thereof

: No. 10573-1U1

### INFORMATION DISCLOSURE STATEMENT

It is requested that the enclosed reference(s) listed on the attached Information Disclosure Citation Form PTO/SB/08/A or B be considered by the Patent Examiner in connection with the above-identified application and be made of record therein.

Independent consideration and acknowledgment of the enclosed reference(s) are respectfully requested.

Respectfully submitted,

Reiner Class et al.

7 October 2002

Date)

Gary D. Colby, Ph.D., J.D.

Registration No. 40,961

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.

One Commerce Square

2005 Market Street - 22nd Floor Philadelphia, PA 19103-7086

Telephone:

215-965-1200

**Direct Dial:** Facsimile:

**215-965-1285** 215-965-1210

E-Mail:

gcolby@akingump.com



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|---|-----|----|----|---|
|   | DEC | 13 | WI |   |

| Form PT0 | D/SB/08A   | Tr.  | C.Y.       | 7                      | Complete if Known | _ |
|----------|------------|--|------------|------------------------|-------------------|---|
|          |            | <b>*</b> * * * * * * * * * * * * * * * * * * | JPANE : ST | Application Number     | 10/049,753        |   |
|          |            |  |            | Filing Date            | 9 August 2000     |   |
| STATE    | MENT BY    | APPLIC                                       | JANI       | First Named Inventor   | Reiner Class      |   |
| luco o   | s many she | ate as pace                                  | occon/\    | Group Art Unit         | Not Yet Assigned  |   |
| (use a   | S many She | ets as new                                   | =55a1y)    | Examiner Name          | Not Yet Assigned  |   |
| Sheet    | 1          | of   | 1          | Attorney Docket Number | 10573-1U1         |   |

|              |                      | U.S                  | S. PATENT DOCUMENTS                             |                        |  |
|--------------|----------------------|----------------------|---|------------------------|--|
| Exr Initials | U.S. Patent Document |                      | Name of Inventor or Applicant of Cited Document | Date of Publication of |  |
|              | Number               | Kind Code (if known) |   | Cited Document MM-YYYY |  |
|              | 5 780 432            | Α                    | Zeppezauer                                      | 07-1998                |  |
|              | 5 182 257            | Α                    | Zeppezauer                                      | 01-1993                |  |
|              | 5 182 257            | A                    | Zeppezauer                                      | 01-1993                |  |

| Exr Initials |                 | Foreign Patent Docume | ent                     |  | Date of                                     | T |
|--------------|-----------------|-----------------------|-------------------------|--|---|---|
|              | Country<br>Code | Number                | Kind Code<br>(if known) | Name of Inventor or Applicant of Cited<br>Document | Publication of<br>Cited Document<br>MM-YYYY |   |
|              | WO              | 99 37318              | A1                      | Samyang Genex Corp.                                | 07-1999                                     |   |
|              | WO              | 97 38713              | A1                      | Regents of the University of<br>California         | 10-1997                                     |   |
|              | DE              | 197 15 149            | A1                      | Symbiotec  | 10-1998                                     |   |
|              | GB              | 563 651               | Α                       | The Trustees of The University of Pennsylvania     | 08-1944                                     |   |
|              | EP              | 0 392 315             | A1                      | Symbiotec  | 10-1990                                     |   |

|                 | OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS   |   |
|-----------------|---|---|
| Exr<br>Initials | Include Name of first Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), volume-issue number(s), page(s), date (in parentheses). If a book, also include publisher and city and/or county where published. | T |
|                 | Ashmarin et al., 1971, & Dokl. Akad. Nauk SSSR, 201(2), 477-9 (abstract only)   |   |
| _               | Ashmarin et al., 1972, & Antibiotiki 17(3), 266-9 (abstract only)   |   |
|                 | Gerchman et al., 1994, Prot. Express. Purif. 5:242-251  |   |
|                 | Hirsch, J.G., J. Experimental Med., JP, Vol. 108, pgs. 925-944,1958   | T |
|                 | Hoffert, 1998, The Scientist 12:6   | T |
|                 | Isenberg, 1979, Annu. Rev. Biochem. 48:159-191  | 1 |
|                 | Linder et al., 1994, Mol. Cell. Biol. 4:2822-2835   |   |
|                 | Murray, 1977, Am. J. Med. 102:284-293   | T |
|                 | Pehrson et al., 1981, Biochemistry 20:2298-2301   |   |
|                 | Rose et al., 1998, Infection and Immunity 66:3255-3263  |   |
|                 | Roth et al., 1997, Appl. Env. Microbiol. 63:2421-2431   |   |

| Examiner  | Date       |
|-----------|------------|
| Signature | Considered |



I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C., 20231, on the date indicated below.

BY: Delane Station

DATE: Chall

PATENT

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Patent Application of

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10/049,753

Group Art Unit:

Filed:

9 August 2000

Not Yet Assigned

For:

Antimicrobial Histone H1 Compositions.

: Attorney Docket

Kits, and Methods of Use Thereof

No. 10573-1U1

#### PRELIMINARY AMENDMENT

Prior to examination on the merits, please amend the patent application referenced above as follows.

### In the Claims:

Please cancel claims 1-37 and substitute new claims 38-84 as follows.

- -- 38. An antimicrobial composition comprising a eukaryotic histone H1 protein.
- 39. The composition of claim 38, wherein the histone H1 protein is substantially purified.
- 40. The composition of claim 39, wherein the histone H1 protein is derivated with polyethylene glycol
  - 41. The composition of claim 38, further comprising a second antibiotic.
- 42. The composition of claim 41, wherein the second antibiotic is selected from the group consisting of histone H2A, histone H2B, histone H3, histone H4, histone H5,



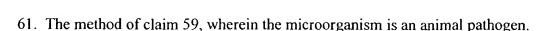
penicillin, streptomycin, vancomycin, bacitracin, polymyxin, neomycin, chloramphenicol, chlortetracycline, ciprofloxacin, tobramycin, erythromycin, genamicin, gramicidin, oxytetracycline, norfloxacin.

- 43. The composition of claim 41, wherein the second antibiotic is in the form of either a salt or an ester.
  - 44. The composition of claim 38, further comprising lysozyme.
- 45. A composition of claim 38, further comprising a pharmaceutically acceptable carrier, wherein the composition is a pharmaceutical composition.
- 46. A kit comprising the composition of claim 45 and an instructional material which describes use of the composition to inhibit growth of a microorganism.
- 47. The kit of claim 46, wherein the instructional material describes use of the composition to kill the microorganism.
- 48. The kit of claim 46, wherein the composition is in the form of a wound dressing.
  - 49. An animal feed comprising the composition of claim 38.
  - 50. A foodstuff supplemented with the composition of claim 38.
- 51. The foodstuff of claim 50, selected from the group consisting of a meat, a fish, a milk, a cheese, a bread, a crop, a beer, and a wine.



- 53. The personal care product of claim 52, selected from the group consisting of a cream, a lotion, a deodorant, a lipstick, a toothpaste, a tooth powder, a dental floss, a mouthwash, a sanitary napkin, a vaginal tampon, and an insole.
  - 54. A medical device coated with the composition of claim 38.
- 55. The medical device of claim 54, selected from the group consisting of a surgical implant, a catheter, an intravenous pump, a wound dressing, a plaster, a sanitary napkin, and a vaginal tampon.
- 56. The medical device of claim 54, wherein the device is a titanium implant having a portion of its surface chemically modified to comprise negatively charged groups and having histone H1 bound therewith.
- 57. A wrap for perishable food, the wrap comprising the composition of claim 38 and at least one of a synthetic polymer and a polymer containing a biological macromolecule.
- 58. The wrap of claim 57, wherein the histone H1 is coupled to at least one surface of the wrap.
- 59. A method of inhibiting growth of a microorganism, the method comprising contacting the microorganism with the composition of claim 38.
- 60. The method of claim 59, wherein the microorganism is resistant to at least one antibiotic.





- 62. The method of claim 61, wherein the microorganism is a human pathogen.
- 63. The method of claim 61, wherein the microorganism is a bacterium.
- 64. The method of claim 63, wherein the bacterium is selected from the group consisting of Escherichia coli, Klebsiella pneumoniae, a Shigella species, Serratia marcesceans, Bacillus cereus, Bacillus subtilis, Pseudomonas aeruginosa, Proteus morgani, Staphylococcus albus, Salmonella typhimurium, Salmonella enteritidis, Proteus mirabilis, and Bacillus megaterium.
- 65. A method of treating a microbial infection of an organism, the method comprising administering the composition of claim 38 to the organism.
  - 66. The method of claim 65, wherein the organism is a plant.
  - 67. The method of claim 65, wherein the organism is an animal.
  - 68. The method of claim 67, wherein the animal is a human.
- 69. The method of claim 67, wherein the composition is administered to the animal either by injection or by infusion into a tissue of the animal.
  - 70. The method of claim 69, wherein the tissue is blood.
- 71. The method of claim 65, wherein the composition is administered to the organism in the form of a wound dressing.



- 72. The method of claim 71, wherein the wound dressing is selected from the group consisting of a crème, a gel, an absorbent material, and a physiologically degradable material.
- 73. A method of preventing a microbial infection of an animal, the method comprising administering the composition of claim 38 to the animal.
- 74. A method of making a vaccine against a microorganism, the method comprising combining the microorganism with the composition of claim 38, whereby the microorganism is attenuated or killed to yield the vaccine.
- 75. A method of immunizing an animal against a microorganism, the method comprising administering to the animal a vaccine made by combining the microorganism with the composition of claim 38.
- 76. A method of coating a medical device with the composition of claim 38, the method comprising covalently linking a coupling group to the surface of the device and contacting the covalently-linked coupling group with histone H1.
- 77. The method of claim 76, wherein the coupling group binds histone H1 either covalently or electrostatically.
- 78. The method of claim 76, wherein the medical device is selected from the group consisting of a surgical implant, a catheter, an intravenous pump, a wound dressing, a plaster, a sanitary napkin, and a vaginal tampon.

- 80. A method of coating a food wrap with the composition of claim 38, the method comprising covalently linking a coupling group to the surface of the wrap and contacting the covalently-linked coupling group with histone H1.
- 81. A method of improving the growth of a non-human animal, the method comprising feeding the animal feed of claim 49 to the animal.
- 82. A method of inactivating histone H1 protein that has been administered to an animal, the method comprising administering heparin to the animal in an amount effective to inactivate the histone H1 protein.
  - 83. The method of claim 82, wherein the animal is a human.
- 84. A method of inactivating heparin in an animal, the method comprising administering to the animal a eukaryotic histone selected from the group consisting of H1, H2A, H2B, H2A:H2B dimer, H3, and H4 in an amount effective to inactivate heparin. --

#### REMARKS

Claims 38-84 are pending following entry of this Preliminary Amendment.

Claims 38, 82, and 84 are the only independent claims. The claims have been amended to place them in more typical U.S. claim format. The amended claims are supported by those originally present in the priority application.



Consideration of the claims and issuance of a favorable office action on the merits are respectfully requested at the earliest possible time.

Respectfully submitted,

Reiner Class et al.

7 October 2102 Byz

Cary D. Colby, Ph.D., J.D.

Registration No. 40,961

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.

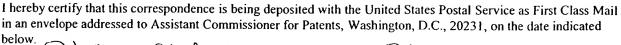
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Stabel DATE: Odober 7, 2002

**PATENT** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in Re:

Patent Application of

Reiner Class et al.

: Attention:

: Box PCT

Conf. No.:

7581

: International Appln. No.

: PCT/US00/21747

Appln. No.:

10/049,753

: Group Art Unit:

Filed:

9 August 2000

Not Yet Assigned

For:

Antimicrobial Histone H1 Compositions,

: Attorney Docket

Kits, and Methods of Use Thereof

: No. 10573-1U1

# STATEMENT REGARDING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE <u>SUBMISSION REQUIREMENT</u>

In the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US), mailed 5 April 2002, the Applicants were instructed to submit a Sequence Listing as a separate part of the disclosure on paper copy or compact disk and to also submit a copy of the Sequence Listing in a computer-readable form.

The Applicants have reviewed the application, and believe that it does not include a nucleotide or amino acid sequence. For this reason, the Applicants believe that submission of a sequence listing is not appropriate for this application.

For the Examiner's information, histone H1-related sequences were known in the art at the time the application was filed (see, e.g., Isenberg, 1979, Annu. Rev. Biochem. 48:159-191).



If the Examiner continues to believe that submission of a sequence listing is appropriate, the Examiner is respectfully requested to point out the sequences disclosed in the specification that should be included in the listing.

Respectfully submitted,

Reiner Class, et al.

By:

October 2002

(Date)

Gary D. Colby, Ph.D., J.D.

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| below.<br>BY:                   | love Habel   | DATE: (Idaler 1, 2002  |    |
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| In Re:                          | Patent Application of Reiner Class et al.  | : Attention:<br>: Box PCT  |    |
| Conf. No.:                      | 7581   | : International Appln. No.<br>: PCT/US00/21747   |    |
| Appln. No.:                     | 10/049,753   | . :  |    |
| Filed:                          | 9 August 2000  | : Group Art Unit:<br>: Not Yet Assigned  |    |
| For:                            | Antimicrobial Histone H1 Composit<br>Kits, and Methods of Use Thereof                    | itions, : Attorney Docket<br>: No. 10573-1U1   |    |
| PF                              | ETITION FOR EXTENSION OF T   | 'IME UNDER 37 C.F.R. §1.136(a)   |    |
| Sunday) for re<br>United States | esponding to the Notification of Missi   | (5 and 6 October 2002 being a Saturday and sing Requirements Under 35 U.S.C. 371 in the US) mailed 5 April 2002. A response to the | )  |
| month extension [X] The C       | ion of time for a small entity.  | 00.  n the above-calculated fee. submitted,  |    |
| 7 Octobe,<br>(Date)             | By: Gary D. Colb<br>Registration N<br>AKIN, GUMI<br>One Commerce<br>2005 Market S        | Ph.D., J.D. No. 40,961 P, STRAUSS, HAUER & FELD, L.L.P. ce Square Street - Suite 2200 PA 19103-7086 215-965-1200                   | _  |

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hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C., 20231, on the date indicated below.

BY: Journ Jan

DATE: December 9 2002

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re:

Patent Application of

: Attention:

Reiner Class et al.

: OIPE

Conf. No.:

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PCT/US00/21747

Appln. No.:

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Group Art Unit:

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For:

Antimicrobial Histone H1 Compositions,

: Attorney Docket

Kits, and Methods of Use Thereof

No. 10573-1U1

#### STATEMENT OF HELENE GABEL

I, Helene Gabel, state that I am the individual whose signature appears beside the date "October 7, 2002" on the Certificate of Mailing atop the enclosed copy of the "Transmittal of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)." It is the ordinary practice in my office, and my ordinary practice, to sign the Certificate of Mailing only when the document on which that Certificate appears, and all enclosures listed on the document, are being deposited with the U.S. Postal Service on the date indicated on the Certificate. It is therefore my belief that the enclosed "Transmittal of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" and the documents referred to therein were deposited by me with the U.S. Postal Service on October 7, 2002.

I understand that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

December 9, 2002

Helene Gabel

Date